

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-2, 4-11, 16, 17, and 43, 44, 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kissinger et al. (USPN 6,062,224) in view of Lang (USPN 5,609,572) or Raines et al. (USPN 5,037,390).

Kissinger et al. discloses at least one syringe (three syringes), at least one fluid reservoir, at least one pinch valve, and at least one catheter, wherein the catheter is disposable (see figures 1 and 12 and columns 19 - 21), but fails to disclose the use of multiple reservoirs in connection with multiple syringes.

Lang discloses a system with multiple syringes having multiple valves and multiple reservoirs. Lang discloses the benefit of having multiple syringes with multiple valves to allow better regulation and control of many different types of medication, especially medication that are incompatible infusion solutions (column 2, lines 17-30). (Figures 7A, 9 and entire reference).

Raines et al. discloses a system of mixing fluids that comprises multiple syringes, valves, and reservoirs to make a precise mixture (figures 1, 2, 15-20 and entire reference).

At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the system Kissinger et al. with Lang or Raines et al. since both Lang and Raines et al. teach the use of multiple reservoirs and syringes to make an effective medication that is going to be used by the patient. Applicant also lacks criticality on the number of syringes and reservoirs that are used in the invention as well as the type of valve being used. Therefore, the examiner has determined that one of ordinary skill could use routine skill and experimentation to modify the Kissinger et al. reference to include multiple syringes, and reservoirs.

***Response to Arguments***

3. Applicant's arguments with respect to the claims have been considered but are not persuasive.
4. The applicant argues that a prima facie case of obviousness hasn't been established. The examiner disagrees on several issues. The first being the examiner's conclusion, and the second being the prior art taken together doesn't teach applicant's invention.
5. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

6. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

7. The examiner uses Kissinger as the primary reference teaching the overall aspect of the invention, but is missing only a couple of aspects of applicant's invention, which the examiner feels are obvious variations that are well known in the fluid handling and/or medical art. The remarks section state that the prior art fails to show the valves (pinch) not in fluid communication with the fluid passing through the tubes, or that the valves are in fluid communication with fluid. According to Kissinger the pinch valves control the fluid flow (Column 7, lines 1-15, Column 21, lines 10-35, Column 24, lines 10-30), and are shown in figure 12 as being located outside the tube section, which is similar to applicant invention as shown in applicant's drawings figures 2-4. With regards to Kissinger not disclosing a drug delivery device, figure 12 shows a reservoir of saline (200), which can be considered a treatment or drug, but if that was not the case, it would be obvious as well as well known to insert medicament or a drug into a reservoir that is going to be inserted into a patient or animal (which is supported by the prior art cited – Lang, and Rains). The controller is described in detail in Columns 21-24 of Kissinger as reference number 204.

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8. The examiner cited Lang and Rains as evidence for the level of skill in the art to show that it is well known to use multiple reservoirs and syringes and valves to control fluid flow and prepare a mixture that is going to be infused into a patient. Therefore, it would have been obvious and taken routine skill in the art to change the number of reservoirs, syringes and valves in Kissinger because of the level of skill in the art that was shown by Lang and Rains as well as the benefits and advantages that are taught by using these techniques.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from, call 800-786-9199 or 571-272-1000.

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